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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :  
TORU MORIGUCHI, ET AL. : EXAMINER: MI, QIUWEN  
SERIAL NO: 10/582,940 :  
FILED: JUNE 15, 2006 : GROUP ART UNIT: 1655  
FOR: FAT COMPOSITION :

PRE-APPEAL BRIEF REQUEST FOR REVIEW

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant respectfully requests review of the final rejection in the above-identified application. The review is requested for the reasons set forth herein. No amendments are being filed with this request. No more than five (5) pages of arguments are provided herewith.

This request is being filed with a Notice of Appeal.

Applicant respectfully submits that the Office erred concluding that claim 16 reads on a single component reaction product. The Office has not established that the plain language which defines the two or more component composition of claim 16, even given its broadest reasonable interpretation consistent with the supporting specification, may properly be interpreted to read on the single component reaction product of a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid, eicosapentaenoic acid,  $\alpha$ -linolenic acid and/or an oil comprising  $\alpha$ -linolenic acid. The Office erred because the plain meaning of the language defining the composition of claim 16 is a composition comprising (1) the phospholipid component and (2) a separate and distinct  $\alpha$ -linolenic acid component that is not chemically bound to the phospholipid.

Claim 16 is directed to:

A composition comprising:  
a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid; and  
 $\alpha$ -linolenic acid and/or an oil comprising  $\alpha$ -linolenic acid (emphasis added).

We emphasize the semicolon because it cannot be ignored.

During a discussion held on August 21, 2008, with their undersigned Representative, the Office indicated that filing a Request for Continued Examination (RCE) and amending claim 16 as follows would likely place the application in condition for allowance:

A composition comprising:  
a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid; and  
 $\alpha$ -linolenic acid and/or an oil comprising  $\alpha$ -linolenic acid,  
wherein said  $\alpha$ -linolenic acid and/or said oil comprising  $\alpha$ -linolenic acid is not linked to said phospholipid.

Requiring the Applicant to file a RCE and pay the fees associated therewith to have such an unnecessary amendment entered is superfluous and unwarranted since the “wherein” phrase does not alter the scope of the claim as currently presented. Moreover, the Office’s rationale for requiring the amendment to claim 16 as shown above is fundamentally flawed as a matter of law.

During the discussion, the Office expressed concern that claim 16 includes the reaction product of the phospholipid component and the  $\alpha$ -linolenic acid component. Claim 16 requires “a phospholipid having an n-3 polyunsaturated fatty acid constituent *selected from the group consisting of* docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid.” One of ordinary skill in the art would recognize from the plain meaning of the claim language that the phrase “selected from the group consisting of” allows the inclusion of only those materials explicitly recited in the group, thereby excluding the presence of any material not specified. See e.g., *In re Gray*, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948).

Moreover, it is a fundamental premise of U.S. patent law that the phrase “selected from the group consisting of” is a “Markush group” that is by its very nature closed. See e.g., *Gillette Co. v. Energizer Holdings Inc.*, 74 USPQ2d 1586, 1589-1591 (Fed. Cir. 2005). It is a fact that  $\alpha$ -linolenic acid is an n-3 (a.k.a., omega-3 or  $\omega$ -3) polyunsaturated fatty acid. As asserted by the undersigned Representative during the discussion, by virtue of  $\alpha$ -linolenic acid not being listed among the n-3 polyunsaturated fatty acids recited in the Markush group,  $\alpha$ -linolenic acid is necessarily excluded as a constituent of the claimed phospholipid, as a matter of law.

It should also be mentioned that the Office holds the view that a phospholipid having  $\alpha$ -linolenic acid as a “constituent” thereof somehow inherently reads on the claimed phospholipid component and  $\alpha$ -linolenic acid component recited in claim 16. Perhaps the Examiner interprets the two component composition as a single component reaction product. The Office should not speculate as to the scope and content of the claimed subject matter in light of the specification. See e.g., *In re Steele, Mills and Leis*, 134 USPQ 292, 295 (CCPA 1962). During patent examination, the claims must be given their broadest reasonable interpretation *consistent with the specification*. See e.g., *Phillips v. AWH Corp.*, 75 USPQ2d 1321 (Fed. Cir. 2005). One of ordinary skill in the art giving claim 16 its broadest reasonable interpretation consistent with the specification would have recognized that the composition of claim 16 comprises the following two separate and distinct components: (1) a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid; and (2)  $\alpha$ -linolenic acid and/or an oil comprising  $\alpha$ -linolenic acid.

Applicants insist that the Office’s assertion that the language of claim 16 includes phospholipids having  $\alpha$ -linolenic acid as an n-3 polyunsaturated fatty acid constituent thereof, absent the presence of the “wherein” phrase proposed by the Examiner, is unreasonable with respect to the plain meaning of the claim and inconsistent with the specification. The language of claim 16 itself makes unmistakably clear that the phospholipid and the  $\alpha$ -linolenic acid are two

separate and distinct components of the claimed composition. Nowhere in the specification is there any disclosure that  $\alpha$ -linolenic acid can be the n-3 polyunsaturated fatty acid constituent of the phospholipid. The specification repeatedly states that the composition comprises: a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid; and  $\alpha$ -linolenic acid and/or an oil comprising  $\alpha$ -linolenic acid (See e.g., page 1, lines 4-8, page 4, lines 19-24, page 6, lines 19-25, page 7, lines 1 and 11-14, page 14, lines 20-23, page 15, Table 1 and lines 11-15, page 17, Table 2, page 18, Table 3).

Other claims in the patent application may also shed light as to the meaning of claim terms. See e.g., *Vitronics Corp. v. Conceptronic, Inc.*, 39 USPQ2d 1573 (Fed. Cir. 1996). Claim 34 is directed to a process for preparing the composition according to claim 16, wherein the process involves dissolving the phospholipid component and the  $\alpha$ -linolenic acid component under stirring. There is no inference that a reaction is taking place between the phospholipid component and the  $\alpha$ -linolenic acid component. The evidence clearly shows that the claimed composition is a mixture of separate and distinct phospholipid and  $\alpha$ -linolenic acid components, as opposed to the  $\alpha$ -linolenic acid reacting with, and being a constituent of, the phospholipid, as alleged by the Office.

Since the Examiners preliminarily indicated that allowable subject matter was presented but were adamant about incorporating the “wherein” phrase into claim 16, Applicant’s representative contacted Examiner Mi on August 22, 2008, to suggest that the “wherein” phrase be incorporated into claim 16 via an Examiner’s amendment to expedite prosecution and avoid the undue expense of filing an RCE. Unfortunately, the Examiner insisted that Applicants file an RCE to have the same entered into the record.

Applicants respectfully submit that the Office’s interpretation of claim 16 is unreasonable with respect to the plain meaning of the claim and inconsistent with the specification. Applicants

suggest that that the “wherein” phrase required by the Office is superfluous and unwarranted since it would not alter the scope of the claimed subject matter as currently presented.

In conclusion, Applicants submit that the claims are now in condition for allowance and notification to this effect is earnestly solicited.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "David P. Stitzel", is written over a horizontal line.

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